

REMARKS

Applicants have received and reviewed the Office Action dated June 2, 2010. By way of response, Applicants have canceled claim 33 without prejudice. Applicants have amended claim 28 and added new claim 35. No new matter has been added. Claims 28-32 and 34-35 are pending.

Applicants submit that the amended and newly presented claims are supported by the specification as filed. In particular, amended claim 28 includes recitations generally corresponding to recitations found in canceled claim 33. Similarly, new claim 35 includes the amount of meglumine recited in claim 32 and recitations generally corresponding to recitations found in canceled claim 33.

For the reasons presented below, Applicants respectfully submit that the amended and newly presented claims are in condition for allowance, and notification to that effect is earnestly solicited.

Rejection of Claims Under 35 U.S.C. § 103(a)

The Examiner rejected claims 28-34 under 35 U.S.C. § 103(a) over Cho, US 6,709,676 in view of Dietrich et al., US 7,175,854 and Faour et al., US 6,605,302. Although this rejection has not been applied to the newly presented claim, it is discussed insofar as it might apply. Applicants respectfully traverse this rejection.

Applicants respectfully submit that the cited references, either singly or in combination, disclose or suggest providing sufficient stability to desloratadine “that after 3 months at 40 °C and 75% relative humidity less than 0.5 %w/w of the N-formyl impurity of desloratadine has formed”, as is recited in independent claims 28 and 33. Further, the cited references fails to disclose or suggest achieving such unexpected stability through the use of the claimed quantity of meglumine. This unexpected stability is demonstrated by working examples in the present application as filed.

The secondary Dietrich et al. reference discloses that a base “prevents possible discolorations” (column 30, line 58) with an acid labile active ingredient. However, the present inventors have observed that the discoloration of desloratadine is not related to the N-Formyl impurity. This is apparent from the examples described in the specification. For example, working Examples 1-6 of the present application found a level of N-Formyl impurity ranging

from 0.03 % to 0.13 % without any pink coloration. In marked contrast, Comparative Examples 1 and 2 in the present application although showed N-Formyl impurity of about 0.19 %, there was a discoloration wherein the tablets turned pink in color. Thus, this secondary reference would not motivate a skilled worker to use meglumine to reduce the formation of the N-formyl impurity.

Each of the independent claims recites the low level of the N-formyl impurity formed over 3 months under accelerated conditions. Thus, the secondary Dietrich et al. reference does not remedy the shortcomings of the primary Cho reference.

Further, Applicants respectfully submit that the obviousness rejection seems to be based on hindsight reconstruction of the present invention. It is axiomatic that for a claimed invention to be found obvious, it must be true that the subject matter sought to be patented as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art (PHOSA) to which said subject matter pertains. The words "sought to be patented" and "as a whole" prohibit piecemeal reconstruction of the invention as claimed from various individual elements found in the prior art, i.e., the claimed structural interconnection and functional interrelationships of the combined elements must be considered. The words "would have been" and "at the time" are intended to emphasize that obviousness should be tested the instant before the invention was made, i.e., it is impermissible to work backwards from the claimed invention to the prior art.

Accordingly, based on the foregoing differences, Applicants submit that the cited references neither teach nor suggest the presently claimed primers, and withdrawal of this rejection is earnestly solicited.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

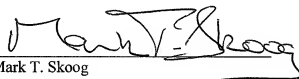
Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

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